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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,379	02/21/2002	Andrew J. Tomlinson	08191-025001	9709
26161	7590	06/28/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER

1653

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,379	Applicant(s) TOMLINSON ET AL.	
	Examiner Robert B Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-25 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

The current application filed on February 21, 2002 claims priority to provisional application 60/270,336 filed February 21, 2001 and provisional application 60//284,416 filed April 16, 2001.

Preliminary Amendment

The preliminary amendment filed June 24, 2002 has been entered.

Information Disclosure Statement

The IDS filed June 24, 2002 has been received and is signed and considered, a copy of the IDS is attached to the following document.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademarks SEPHAROSE (page 5, line 18), DIAZALD (page 18, line 16), SPEEDVAC (page 20, line 5), PICO TIP (page 26, line 28) have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 25**, "HPLC" and C2, C4, C8, C18 need to be spelled out in the first instance of use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt et al. Hunt et al. teach a methodology for determining peptide sequences by tandem mass spectrometry, this approach involves the chemical degradation of the peptide into methyl esters, using an acidified alcohol such as methanol, and hence creating a collection of peptides which are then fractionated by HPLC and analyzed by mass spectroscopy (page 6233, columns 1-2 and Materials and Methods). Hunt et al teach further that the concentration of the peptide species is less than 1 nM (Materials and Methods) (**present claims 1-8**). Thus Hunt et al. teach all the elements of **claims 1-8** and these claims are anticipated under 35 USC 102(b).

Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Osbahr. Osbahr teaches a method of preparing peptide methyl esters involving the use of diazomethane and alcohol (Materials and Methods, page 184) (**present claims 9-10**). Thus Osbahr et al. teach all the elements of **claims 9-10** and these claims are anticipated under 35 USC 102(b).

Claims 12-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Goodlett et al. Goodlett et al. teach a method of differential isotopic esterification providing the ability to derive peptide sequence by comparison of d0- to d3- methyl esters of a given peptide wherein the concentration of the peptide species is less 1 nM. Goodlett et al. teach further that the first population of esters comprises methyl esters, the second population of labeled peptides comprises methyl esters labeled with oxygen 18 and are esterified using a substituted alcohol. Goodlett et al. also teach that the first and second sample comprise biological material derived from tissue types. Goodlett et

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al. teach that the determining step of their method comprises ascertaining the ratio of hydrogen in the first population of peptide esters to deuterium in the second population of isotopically labeled peptide esters and sequencing the peptide species after determining the relative quantity of the peptide species (Methyl esterification, Mass Spectrometry, Quantification, de novo Sequencing page 1215-1219) (**present claims 12-21**). Thus Goodlett et al. teach all the elements of **claims 12-21** and these claims are anticipated under 35 USC 102(a).

Claims 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodlett et al. United States Patent Application Publication US2002/0115056 A1. Goodlett et al. teach a method of differential isotopic esterification providing the ability to derive peptide sequences by comparison of d0- to d3- methyl esters of a given peptide wherein the concentration of the peptide species is less 1 nM. Goodlett et al. teach further that the first population of esters comprises methyl esters, the second population of labeled peptides comprises methyl esters labeled with oxygen 18 and is esterified using a substituted alcohol. Goodlett et al. also teach that the first and second sample comprise biological material derived from tissue types. Goodlett et al. teach that the determining step of their method comprises ascertaining the ratio of hydrogen in the first population of peptide esters to deuterium in the second population of isotopically labeled peptide esters and sequencing the peptide species after determining the relative quantity of the peptide species (section 0008, 0015, 0019, 0021, 0031, 0037, 0041, 0043, 0045, 0060 and examples 1-3) (**present claims 12-21**). Thus Goodlett et al. teach all the elements of **claims 12-21** and these claims are anticipated under 35 USC 102(a).

Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Vallee et al. US Patent 4,987,1990. Vallee et al. teach a method of fractioning and separating peptides using a strong cat ion exchanger wherein the peptides are absorbed onto a reversed phase HPLC column and eluted by an increasing acetonitrile concentration gradient. Valee et al. teach further that the eluted peptides are sequenced by mass spectrometry (column 4, lines 10-44 and column 11, lines 45-52) (**present claims 22-25**). Thus Vallee et al. teach all the elements of **claims 22-25** and these claims are anticipated under 35 USC 102(b).

Claims 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Brader et al. US Patent 6,268,335. Brader et al. teach a method of fractioning and separating peptides using a strong cat ion exchanger wherein the peptides are absorbed onto a reversed phase HPLC column and eluted by an increasing acetonitrile concentration gradient. Brader et al. teach further that the eluted peptides are sequenced by mass spectrometry (column 28, lines 18-62, and column 30, lines 65-67) (**present claims 22-25**). Thus Barder et al. teach all the elements of **claims 22-25** and these claims are anticipated under 35 USC 102(e).

Conclusion

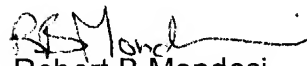
No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B Mondesi
Patent Examiner
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06-22-04


ROBERT A. WAX
PRIMARY EXAMINER